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PTO/SB/21 (02-04)

Approved for use through 07/31/2006. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	<b>10/767,784</b>
	Filing Date	<b>January 29, 2004</b>
	First Named Inventor	<b>Galley et al.</b>
	Art Unit	<b>1624</b>
	Examiner Name	<b>Ward, Paul, V.</b>
Total Number of Pages in This Submission	Attorney Docket Number	<b>21453</b>

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance communication to Group
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Change of Correspondence Address	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Terminal Disclaimer	
<input type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> Request for Refund	
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> CD, Number of CD(s) _____	
<input type="checkbox"/> Response to Missing Parts/Incomplete Application	Remarks	
<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<b>-Petition Under 37 C.F.R. Section 1.144; and</b> <b>-Exhibits A-C</b>	

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT	
Firm or Individual name	<b>Kimberly J. Prior</b>
Signature	
Date	<b>10/24/2006</b>

CERTIFICATE OF TRANSMISSION/MAILING	
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.	
Typed or printed name	<b>Kimberly J. Prior</b>
Signature	
Date	<b>10/24/2006</b>

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application

Inventors: Galley et al.

Group: 1624

Serial No. 10/767,784, filed January 29, 2004  
(Ref. No. 21453 US)

Examiner: WARD, Paul V.

For: **MALONAMIDE DERIVATIVES**

**PETITION UNDER 37 C.F.R. § 1.144**

Nutley, New Jersey 07110  
October 24, 2006

**Mail Stop: Box AF**  
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Applicants respectfully petition under 37 C.F.R. § 1.144 for withdrawal of the Restriction Requirement issued May 5, 2006, and made final in the Ex parte Quayle action issued August 25, 2006, and further examination of the claims to the extent necessary to determine patentability of the generic/linking claim.

A petition to the Director is proper because reconsideration of the Restriction Requirement was requested in the response filed June 5, 2006, and the Restriction Requirement was then made final and prosecution on the merits closed in the first substantive Office Action issued August 25, 2006.

Serial No. 10/767,784  
Filed: January 29, 2004

In accordance with 37 C.F.R. § 1.181, the following is a statement of the facts involved, points to be reviewed, and action requested.

*Facts Involved*

The instant application was filed January 29, 2004. On May 5, 2006, a Restriction Requirement (**Exhibit A**) was issued dividing the claims into 42 groups as follows:

Groups I to VII are directed to compounds of claim 1 having formula IA, wherein the definition of the C ring is different for each group.

Groups VIII to XIV are directed to compounds of claim 1 having formula IB, wherein the definition of the C ring is different for each group.

Groups XV to XXI are directed to processes for preparing the compounds of formula IA recited in claims 22 and 24.

Groups XXII to XXVIII are directed to processes for preparing the compounds of formula IB recited in claim 23.

Groups XXIX to XXXV are directed to methods of using compounds of formula IA recited in claim 20.

Groups XXXVI to XLII are directed to methods of using compounds of formula IB recited in claim 21.

This intraclaim restriction requirement was traversed in terms of election of species, but can be equally considered in terms of linking claims. (**Exhibit B**) In a First Office Action issued August 25, 2006 (**Exhibit C**), the Restriction Requirement was made final and the Patent Office indicated that “groups II-XLII are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking

claim.” (emphasis added) The Office Action further states that “This application is in condition for allowance except for the presence of non-elected subject matter in the claims.... Prosecution on the merits is closed in accordance with Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.”

Points for Review

- ◆ Whether in view of the facts of this application, it was improper for the Patent Office to close prosecution on the merits and allege that there is no allowable generic/linking claim without actually extending search and examination to determine the patentability of such generic/linking claim.

M.P.E.P. § 809 Linking Claims

Applicants submit that Claim 1 is generic to and links the compounds indicated in Groups I to XIV of the Restriction Requirement May 5, 2006. For example, Group I encompasses compounds where C is phenyl. Claim 5 and those which depend from it recite compounds where C is phenyl. Group III encompasses compounds where C is furanyl or tetrahydrofuranyl. Claim 7 recites compounds where C is furanyl. Group IV encompasses compounds where C is benzo[b]thiophenyl. Claim 7 also encompasses compounds where C is benzo[b]thiophenyl. Claim 1 is generic to and links all of these and the other claims in the application.

M.P.E.P. § 809 provides the procedure for restriction and examination of an application containing linking claims. This section provides that “the linking claims must be examined with, and thus are considered part of, the invention elected. When all claims directed to the elected invention are allowable, should any linking claim be allowable, the restriction requirement between the linked inventions must be withdrawn. Any claim(s) directed to the non-elected invention(s), previously withdrawn from consideration, which depends from or requires all the limitations of the allowable linking claim must be rejoined and will be fully examined for patentability.”

Serial No. 10/767,784  
Filed: January 29, 2004

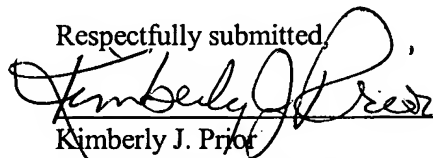
In the present application, it appears that the linking claim was not examined with the elected invention as required. In other words, it appears that the claims were examined only to the extent that they included compounds where C is phenyl. When no art was found, examination on the merits was closed, and applicant was informed that the elected invention was allowable. Although the Office Action states that no linking claim is allowable, there is no indication on the record that the linking claim was actual examined and no reasons have been provided as to why the generic/linking claim is not allowable. Applicants respectfully submit that the actions taken in the present application are inconsistent with Patent Office policy and that prosecution on the merits has been prematurely terminated.

Action Requested

Applicants hereby petition the Director to reopen prosecution on the merits, withdraw the Restriction Requirement issued May 5, 2006, and require search and examination of the claims as filed January 29, 2004, to the extent necessary to determine patentability of the generic/linking claim.

It does not appear that there is any fee associated with the filing of this petition. However, the Director is hereby authorized to charge any deficit, or credit any overpayment, to Deposit Account No. 08-2525.

Respectfully submitted,



Kimberly J. Prior  
Attorney for Applicant(s)  
(Reg. No. 41,483)  
340 Kingsland Street  
Nutley, New Jersey 07110  
Telephone: (973) 235-6208  
Telefax: (973) 235-2363

267097



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/767,784

01/29/2004

Guido Galley

21453 US

7288

151 7590 05/05/2006

HOFFMANN-LA ROCHE INC.  
PATENT LAW DEPARTMENT  
340 KINGSLAND STREET  
NUTLEY, NJ 07110

EXAMINER

WARD, PAUL V

ART UNIT

PAPER NUMBER

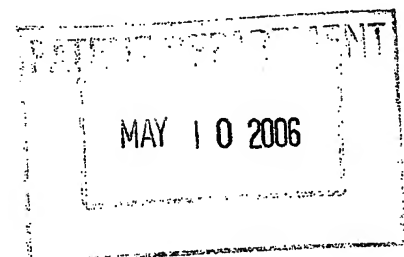
1624

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Restriction
RESPONSE DUE: <u>June 5, 2006</u>
(3 mths)
STATUTORY
PERIOD EXPIRES: <u>Sept. 5, 2006</u>

bak



Copy Sent to  
Department PLP

**Office Action Summary**

Application No.

10/767,784

Applicant(s)

GALLEY ET AL.

Examiner

PAUL V. WARD

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. The compounds according to claim 1 of formula IA, wherein C is phenyl.  
These are classifiable in class 540, subclass various.
- II. The compounds according to claim 1 of formula IA, wherein C is pyridinyl.  
These are classifiable in class 544, subclass 1+.
- III. The compounds according to claim 1 of formula IA, wherein C is furanyl or tetrahydrofuranyl. These are classifiable in class 549, subclass various.
- IV. The compounds according to claim 1 of formula IA, wherein C is benzo[b]thiophenyl. These are classifiable in class 540, subclass various.
- V. The compounds according to claim 1 of formula IA, wherein C is tetrahydronaphthyl. These are classifiable in class 540, subclass various.
- VI. The compounds according to claim 1 of formula IA, wherein C is indanyl.  
These are classifiable in class 548, subclass various.
- VII. The compounds according to claim 1 of formula IA, wherein C is 2,2-dimethyl-[1,3] dioxolanyl. These are classifiable in class 544, subclass various.
- VIII. The compounds according to claim 1 of formula IB, wherein C is phenyl.  
These are classifiable in class 540, subclass various.
- IX. The compounds according to claim 1 of formula IB, wherein C is pyridinyl.  
These are classifiable in class 546, subclass various.



- X. The compounds according to claim 1 of formula IB, wherein C is furanyl or tetrahydrofuranyl. These are classifiable in class 549, subclass various.
  - XI. The compounds according to claim 1 of formula IB, wherein C is benzo[b]thiophenyl. These are classifiable in class 549, subclass various.
  - XII. The compounds according to claim 1 of formula IB, wherein C is tetrahydronaphthyl. These are classifiable in class 540, subclass various.
  - XIII. The compounds according to claim 1 of formula IB, wherein C is indanyl. These are classifiable in class 548, subclass various.
  - XIV. The compounds according to claim 1 of formula IB, wherein C is 2,2, dimethyl-[1,3] dioxolanyl. These are classifiable in class 549, subclass various.
- 
- XV. The process for preparing a compound formula IA according to claim 22, wherein C is phenyl.
  - XVI. The process for preparing a compound formula IA according to claim 22, wherein C is pyridinyl. These are classifiable in class 544, subclass 1+.
  - XVII. The process for preparing a compound formula IA according to claim 22, wherein C is furanyl or tetrahydrofuranyl. These are classifiable in class 549, subclass various.
  - XVIII. The process for preparing a compound formula IA according to claim 22, wherein C is benzo[b]thiophenyl. These are classifiable in class 540, subclass various.

- XIX. The process for preparing a compound formula IA according to claim 22, wherein C is tetrahydronaphthyl. These are classifiable in class 540, subclass various.
- XX. The process for preparing a compound formula IA according to claim 22, wherein C is indanyl. These are classifiable in class 548, subclass various.
- XXI. The process for preparing a compound formula IA according to claim 22, wherein C 2,2, dimethyl-[1,3] dioxolanyl. These are classifiable in class 544, subclass various.
- XXII. The process for preparing a compound formula IB according to claim 23, wherein C is phenyl.
- XXIII. The process for preparing a compound formula IB according to claim 23, wherein C is pyridinyl. These are classifiable in class 544, subclass 1+.
- XXIV. The process for preparing a compound formula IB according to claim 23, wherein C is furanyl or tetrahydrofuranyl. These are classifiable in class 549, subclass various.
- XXV. The process for preparing a compound formula IB according to claim 23, wherein C is benzo[b]thiophenyl. These are classifiable in class 540, subclass various.
- XXVI. The process for preparing a compound formula IB according to claim 23, wherein C is tetrahydronaphthyl. These are classifiable in class 540, subclass various.

XXVII. The process for preparing a compound formula IB according to claim 23, wherein C is indanyl. These are classifiable in class 548, subclass various.

XXVIII The process for preparing a compound formula IB according to claim 23, wherein C is 2,2, dimethyl-[1,3] dioxolanyl. These are classifiable in class 544, subclass various.

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XXIX. The method of treating according to claims 20-21 of formula IA, wherein C is phenyl. These are classifiable in class 514.

XXX. The method of treating according to claims 20-21 of formula IA, wherein C is pyridinyl. These are classifiable in class 514.

XXXI The method of treating according to claims 20-21 of formula IA, wherein C is furanyl or tetrahydrofuranyl. These are classifiable in class 514.

XXXII. The method of treating according to claims 20-21 of formula IA, wherein C is benzo[b]thiophenyl. These are classifiable in class 514.

XXXIII The method of treating according to claims 20-21 of formula IA, wherein C is tetrahydronaphthyl. These are classifiable in class 514.

XXXIV The method of treating according to claims 20-21 of formula IA, wherein C is indanyl. These are classifiable in class 514.

XXXV The method of treating according to claims 20-21 of formula IA, wherein C is 2,2, dimethyl-[1,3] dioxolanyl. These are classifiable in class 514.

Art Unit: 1624

- XXXVI. The method of treating according to claims 20-21 of formula IB, wherein C is phenyl. These are classifiable in class 514.
- XXXVII. The method of treating according to claims 20-21 of formula IB, wherein C is pyridinyl. These are classifiable in class 514.
- XXXVIII. The method of treating according to claims 20-21 of formula IB, wherein C is furanyl or tetrahydrofuranyl. These are classifiable in class 514.
- XXXIX. The method of treating according to claims 20-21 of formula IB, wherein C is benzo[b]thiophenyl. These are classifiable in class 514.
- XL The method of treating according to claims 20-21 of formula IB, wherein C is tetrahydronaphthyl. These are classifiable in class 514.
- XLI. The method of treating according to claims 20-21 of formula IB, wherein C is indanyl. These are classifiable in class 514.
- XLII The method of treating according to claims 20-21 of formula IB, wherein C is 2,2, dimethyl-[1,3] dioxolanyl. These are classifiable in class 514.

Inventions in Groups I-XIV and Groups XXIX-XLII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the

instant case, the process for using the product as claimed can be practiced with another materially different process, such as inhibiting secretase.

Inventions of Group I-XIV and XV-XXVIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process as claimed can be used to make another and materially different products, such as malonamide derivatives.

The inventions of Groups I-XLII are separate and patentably distinct because there is no patentable co-action among them and a reference anticipating or rendering obvious one member will not anticipate or render another obvious.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different classification, a search of the forty-two groups designated above would impose an undue burden upon the examiner, and restriction for examination purposes as indicated is proper.

A telephone call was made to Kimberly Prior on May 1, 2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is requested to **elect a specifically disclosed species** of the invention to be examined for search purposes.

Art Unit: 1624

**Rejoinder Advisory**

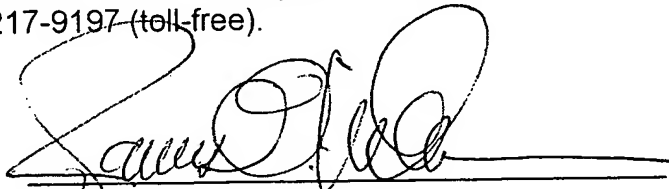
The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for **rejoinder**. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be **rejoined**.

In the event of **rejoinder**, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the **rejoined** process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL V WARD whose telephone number is 571-272-2909. The examiner can normally be reached on M-F 8 am to 4 pm.

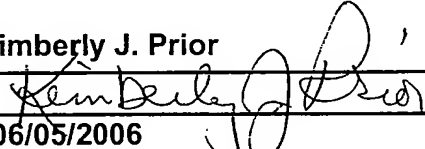
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

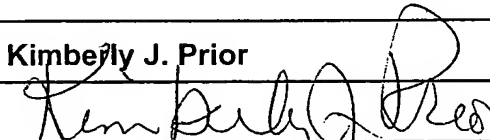
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



James O. Wilson  
Supervisory Patent Examiner  
Technology Center 1600

<b>TRANSMITTAL FORM</b>  <i>(to be used for all correspondence after initial filing)</i>	Application Number	<b>10/767,784</b>
	Filing Date	<b>January 29, 2004</b>
	First Named Inventor	<b>Galley</b>
	Art Unit	<b>1614</b>
	Examiner Name	<b>Ward, Paul V</b>
Total Number of Pages in This Submission	Attorney Docket Number	<b>21453</b>

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input checked="" type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input type="checkbox"/> Other Enclosure(s) (please identify below):
Remarks		
<b>SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT</b>		
Firm or Individual name	<b>Kimberly J. Prior</b>	
Signature		
Date	<b>06/05/2006</b>	

CERTIFICATE OF TRANSMISSION/MAILING			
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.			
Typed or printed name	<b>Kimberly J. Prior</b>		
Signature		Date	<b>06/05/2006</b>

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application

Inventors: Galley, et al.

Group: 1614

Serial No. 10/767,784, filed January 29, 2004  
(Ref. No. 21453)

Examiner: Ward, Paul V.

For: **MALONAMIDE DERIVATIVES**

**RESPONSE TO RESTRICTION REQUIREMENT**

Nutley, New Jersey 07110

Date: June 5, 2006

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

This election is filed in response to the Restriction Requirement issued May 5, 2006, in connection with the above-identified patent application. A response to this Restriction Requirement is due June 5, 2006. Applicants respectfully request consideration of the following remarks.

Claims 1 to 24 are pending. The claims have been restricted to the following forty-two groups.

- I. The compounds according to claim 1 of formula IA, wherein C is phenyl.
- II. The compounds according to claim 1 of formula IA, wherein C is pyridinyl.
- III. The compounds according to claim 1 of formula IA, wherein C is furanyl or tetrahydrofuranyl.

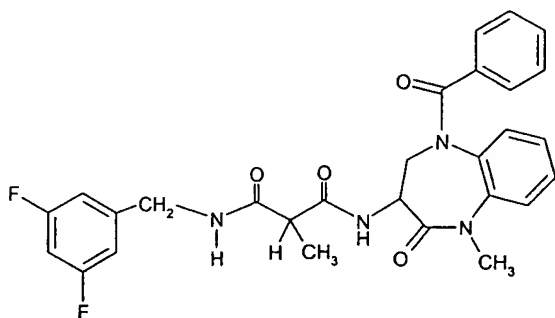


- IV. The compounds according to claim 1 of formula IA, wherein C is benzo[b]thiophenyl.
- V. The compounds according to claim 1 of formula IA, wherein C is tetrahydronaphthyl.
- VI. The compounds according to claim 1 of formula IA, wherein C is indanyl.
- VII. The compounds according to claim 1 of formula IA, wherein C is 2,2,dimethyl-[1,3]dioxolanyl.
- VIII. The compounds according to claim 1 of formula IB, wherein C is phenyl.
- IX. The compounds according to claim 1 of formula IB, wherein C is pyridinyl.
- X. The compounds according to claim 1 of formula IB, wherein C is furanyl or tetrahydrofuranyl.
- XI. The compounds according to claim 1 of formula IB, wherein C is benzo[b]thiophenyl.
- XII. The compounds according to claim 1 of formula IB, wherein C is tetrahydronaphthyl.
- XIII. The compounds according to claim 1 of formula IB, wherein C is indanyl.
- XIV. The compounds according to claim 1 of formula IB, wherein C is 2,2,dimethyl-[1,3]dioxolanyl.
- XV. The process for preparing a compound formula IA according to claim 22, wherein C is phenyl.
- XVI. The process for preparing a compound formula IA according to claim 22, wherein C is pyridinyl.
- XVII. The process for preparing a compound formula IA according to claim 22, wherein C is furanyl or tetrahydrofuranyl
- XVIII. The process for preparing a compound formula IA according to claim 22, wherein C is benzo[b]thiophenyl.
- XIX. The process for preparing a compound formula IA according to claim 22, wherein C is tetrahydronaphthyl.
- XX. The process for preparing a compound formula IA according to claim 22, wherein C is indanyl.

- XXI. The process for preparing a compound formula IA according to claim 22, wherein C is 2,2, dimethyl-[1,3] dioxolanyl.
- XXII. The process for preparing a compound formula IB according to claim 23, wherein C is phenyl.
- XXIII. The process for preparing a compound formula IB according to claim 23, wherein C is pyridinyl.
- XXIV. The process for preparing a compound formula IB according to claim 23, wherein C is furanyl or tetrahydrofuranyl.
- XXV. The process for preparing a compound formula IB according to claim 23, wherein C is benzo[b]thiophenyl.
- XXVI. The process for preparing a compound formula IB according to claim 23, wherein C is tetrahydronaphthyl.
- XXVII. The process for preparing a compound formula IB according to claim 23, wherein C is indanyl.
- XXVIII. The process for preparing a compound formula IB according to claim 23, wherein C is 2,2, dimethyl-[1,3]dioxolanyl.
- XXIX. The method of treating according to claims 20-21 of formula IA, wherein C is phenyl.
- XXX. The method of treating according to claims 20-21 of formula IA, wherein C is pyridinyl.
- XXXI. The method of treating according to claims 20-21 of formula IA, wherein C is furanyl or tetrahydrofuranyl.
- XXXII. The method of treating according to claims 20-21 of formula IA, wherein C is benzo[b]thiophenyl.
- XXXIII. The method of treating according to claims 20-21 of formula IA, wherein C is tetrahydronaphthyl.
- XXXIV. The method of treating according to claims 20-21 of formula IA, wherein C is indanyl.
- XXXV. The method of treating according to claims 20-21 of formula IA, wherein C is 2,2, dimethyl-[1,3] dioxolanyl.
- XXXVI. The method of treating according to claims 20-21 of formula IB, wherein C is phenyl.

- XXXVII. The method of treating according to claims 20-21 of formula IB, wherein C is pyridinyl.
- XXXVIII. The method of treating according to claims 20-21 of formula IB, wherein C is furanyl or tetrahydrofuranyl.
- XXXIX. The method of treating according to claims 20-21 of formula IB, wherein C is benzo[b]thiophenyl.
- XL. The method of treating according to claims 20-21 of formula IB, wherein C is tetrahydronaphthyl.
- XLI. The method of treating according to claims 20-21 of formula IB, wherein C is indanyl.
- XLII. The method of treating according to claims 20-21 of formula IB, wherein C is 2,2-dimethyl-[1,3] dioxolanyl.

Applicants hereby elect with traverse Group I, claims 1 to 6, 9 to 14, and 17 to 19, directed to compounds of formula IA wherein C is phenyl and compositions containing them, and the species N-(5-Benzoyl-1-methyl-2-oxo-2,3,4,5-tetrahydro-1H-benzo[b][1,4]diazepin-3-yl)-N'-(3,5-difluorobenzyl)-2-methyl-malonamide (Example 14), having the following structure:



. Claims 1 to 3, 11, 12, and 17 to 19 read on the elected species.

The requirements are traversed for the following reasons. Upon an election of species, M.P.E.P. § 803.02 states that if no prior art is found that anticipates or renders obvious the elected species, search and examination of the claims will be extended to the extent necessary to

Serial No. 10/767,784  
Filed: January 29, 2004

determine patentability of the generic claim. Thus, Applicants understand that if no art is found which anticipates or renders obvious the elected species, search and examination will be expanded to the extent necessary to determine patentability of the generic claim or at least to the extent necessary to determine patentability of Group I.

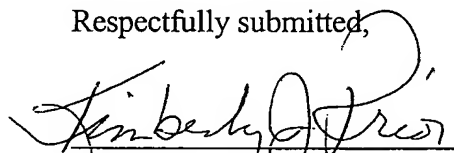
Further, method claims 20 to 24 have been restricted from the product claims as Groups XV to XLII. In accordance with M.P.E.P. § 821.04, Applicants understand that upon the finding of an allowable compound claim, those claims of Groups XV to XLII having all of the limitations of the allowable product claim will be rejoined and examined on the merits.

The foregoing amendment is fully responsive to the Restriction Requirement issued May 5, 2006. Early and favorable consideration is earnestly solicited.

No additional fees are believed due. However, the Director is hereby authorized to charge any deficit, or credit any overpayment, to Deposit Account No. 08-2525.

If the Examiner believes there are other issues that can be resolved by telephone interview, or that there are any informalities remaining in the application which may be corrected by Examiner's Amendment, a telephone call to the undersigned attorney is respectfully solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Kimberly J. Prior", is written over a horizontal line.

Kimberly J. Prior  
Attorney for Applicant(s)  
(Reg. No. 41,483)  
340 Kingsland Street  
Nutley, New Jersey 07110  
Telephone: (973) 235-6208  
Telefax: (973) 235-2363

Express Mail No. \_\_\_\_\_

Date Mailed: JUNE 5, 2006

Docket No. 21453 Ser. No. 10/767,784 Filed: 1-29-2004

Galley, et. al.

MALONAMIDE DERIVATIVES

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|--|--|
| <input type="checkbox"/> Affidavit/Declaration                               | <input type="checkbox"/> Fee Sheet   |
| <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Final | <input type="checkbox"/> Info Discl. State <input type="checkbox"/> Suppl. |
| <input type="checkbox"/> Application _____ pages                             | <input type="checkbox"/> w/refs. <input type="checkbox"/> w/o refs.        |
| _____ Claims _____ Drawings  | <input type="checkbox"/> Letter/Response                                   |
| <input type="checkbox"/> Application Data Sheet                              | <input type="checkbox"/> Petition to Extend Time                           |
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| <input type="checkbox"/> Drawings, formal                                    | <input type="checkbox"/> Transmittal Letter                                |
| _____ Sheets _____ Figures   |  |
| <input type="checkbox"/> Other: _____  |  |

Ref. No.

KTP:LM  
F/0-6-15

SN 10/767,784

ATTY. KTP

SEC. LM

DOCKETED 21453

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,784	01/29/2004	Guido Galley	21453 US	7288

151 7590 08/25/2006

HOFFMANN-LA ROCHE INC.  
PATENT LAW DEPARTMENT  
340 KINGSLAND STREET  
NUTLEY, NJ 07110

EXAMINER

WARD, PAUL V

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

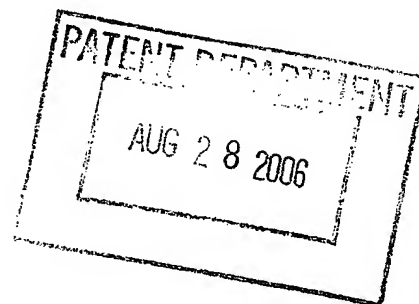
*Ex parte Quaple*

*Restriction (2-17th)*

**RESPONSE DUE:** *October 25, 2006*

**STATUTORY PERIOD EXPIRES:** *January 25 2007*

*→ February 25, 2007* *bkh*



Copy Sent to  
Department PLP

**Office Action Summary**

Application No.

10/767,784

Applicant(s)

GALLEY ET AL.

Examiner

PAUL V. WARD

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 07 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 15-16 & 20-24 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-14, 17-19 is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group I in the reply filed on June 7, 2006 is acknowledged. The traversal is on the ground that the search and examination should be expanded to determine patentability of the generic claim. This is not found persuasive because Groups I-XLII are separate and patentably distinct because there is no patentable co-action among them. For example when C is a phenyl moiety or when C is a pyridinyl moiety, a reference anticipating one will not render the other obvious. Hence, Applicant's inventions are distinct and have acquired a separate status in the art due to their recognized divergent subject matter and different classification. Additionally, because each group has different subclasses, it would constitute a burden on the Examiner to search all subclasses. Further, different fields of search would be required in the non-patent literature. Thus, a search of the forty-two groups would impose an undue burden upon the Examiner. Therefore, the restriction for examination purposes as indicated is proper. The requirement is still deemed proper and is therefore made FINAL.

Groups II-XLII are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant reserved the right to file a divisional application to the non-elected subject matter.



Applicant is entitled to have Groups XV and XXIX rejoined under M.P.E.P. § 821.04, since the claims of Group I are allowable. An amendment, which results in the method claims being commensurate in scope with the allowed claims, will be welcomed.

An action on the merits on claims 1-14 and 17-19 is contained herein.

### ***Conclusion***

This application is in condition for allowance except for the presence of non-elected subject matter in the claims.

The prior art does not teach any of the malonamide compounds substituted in the manner claimed by the Applicant. Thus, the compounds in Group I were neither found to be obvious nor anticipated by the prior art of record. The prior art does not teach or suggest the presently claimed compound.

Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.


A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

Art Unit: 1624

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL V WARD whose telephone number is 571-272-2909. The examiner can normally be reached on M-F 8 am to 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



James O. Wilson  
Supervisory Patent Examiner  
Technology Center 1600

<b>Notice of References Cited</b>	Application/Control No. 10/767,784	Applicant(s)/Patent Under Reexamination GALLEY ET AL.	
	Examiner PAUL V. WARD	Art Unit 1624	Page 1 of 1

**U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
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	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

**FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
*	N	WO01/77086	10-2001	WIPO	Han et al.	C07D 243/24
	O					
	P					
	Q					
	R					
	S					
	T					

**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
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	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
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